Overview of CDRH Premarket and Postmarket Process

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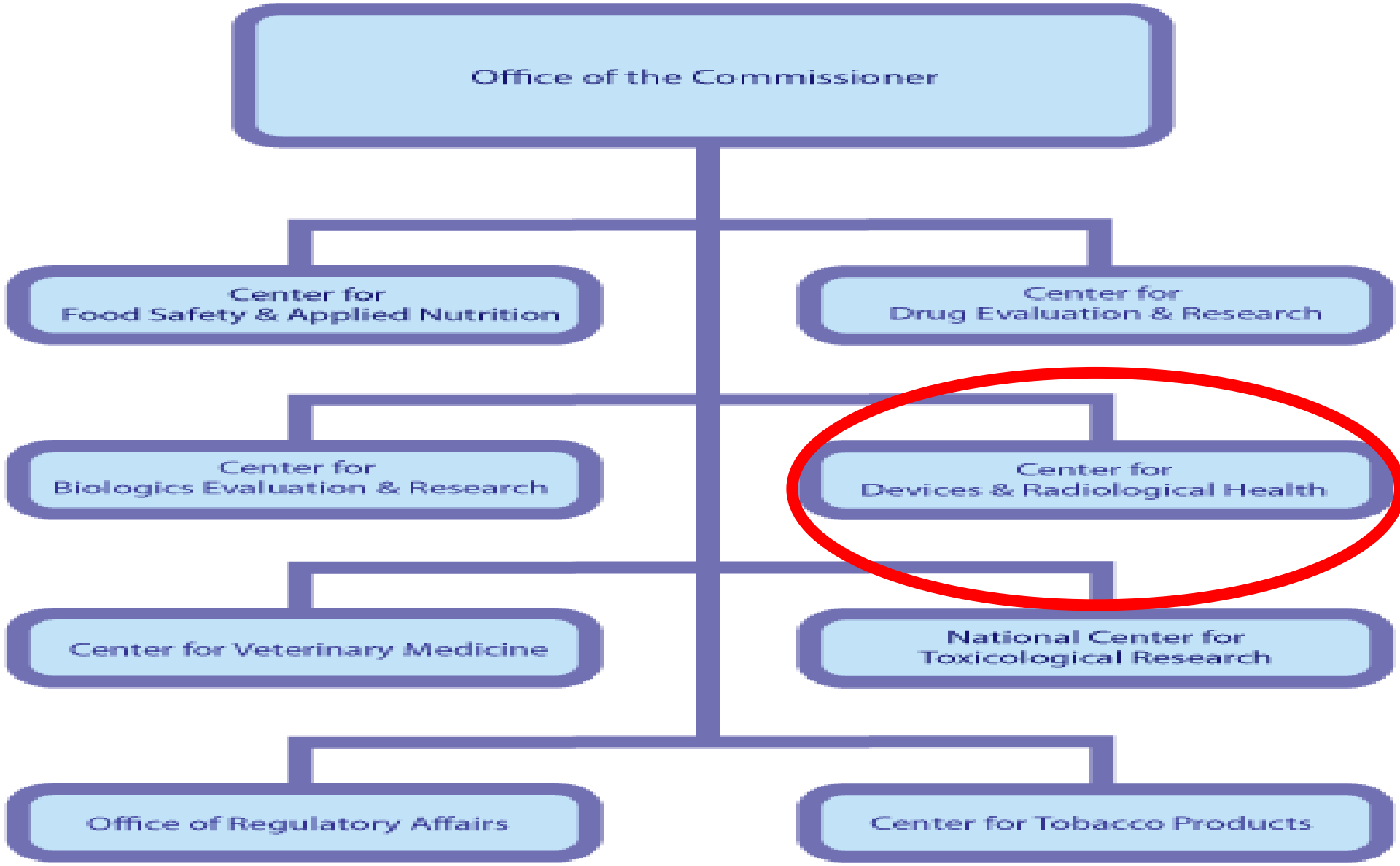
Office of the Commissioner
Center for
Food Safety & Applied Nutrition
Center for
Drug Evaluation & Research
Center for
Biologics Evaluation & Research
Center for
Devices & Radiological Health
Center for Veterinary Medicine
National Center for
Toxicological Research
Office of Regulatory Affairs
Center for Tobacco Products

Overview of Device Regulation

- CDRH is responsible for regulating firms which manufacture, repackage, relabel, and/or import medical devices sold in the United States.
- CDRH regulates radiation-emitting medical and non-medical electronic products such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.

Medical Devices are Classified as Class I, II, and III

Regulatory control increases from Class I to Class III

- Most Class I devices are exempt from Premarket Notification 510(k)
- Most Class II devices require Premarket Notification 510(k)
- Most Class III devices require Premarket Approval

Device Classification

- Depends
  - intended use
  - indications for use
  - risk to patient
  - risk to user
- Class I includes devices with the lowest risk and Class III includes those with the greatest risk
- 74% of the Class I devices are exempt from the premarket notification process

Office of Device Evaluations

- Responsible for the evaluation of premarket submissions from the medical device industry

- Plans, coordinates, and renders Agency decisions regarding marketing medical devices in the United States

Office of Device Evaluation *(cont)*

Four types of premarket submissions:

- Premarket notification submissions known as 510(k)s
- Premarket approval applications (PMAs)
- Product development protocols (PDPs)
- Humanitarian device exemption applications (HDEs)

Office of Surveillance and Biometrics

- Responsible for the evaluation of postmarket device safety and effectiveness once the device is on the market

Office of Surveillance and Biometrics

Receives and Evaluates Adverse Events

- MAUDE Database Search
- MedSun Reports

Postmarket Safety Communications

- Medical Device Safety Communications
- Public Health Notifications (Clinicians)
- Patient Alerts (Devices)
- MedSun Newsletters
- FDA Patient Safety News Video Broadcasts

Office of Surveillance and Biometrics *(cont)*

Postmarket Studies

- Post Approval Studies Status
- 522 Postmarket Surveillance Studies Listing

What is a Guidance Document ?

- Represents FDA's current thinking on a topic
- Does not create or confer any rights for or on any person
- Does not operate to bind FDA or the public
- Alternative approaches are allowed

Guidance Documents

- In general there are two types
  - General
    - Non binding recommendations to manufacturers
  - Special Control
    - More prescriptive

Guidance for Industry and FDA Staff

Total Product Life Cycle: Infusion Pump - Premarket Notification [510(k)] Submissions

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
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Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

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For questions regarding assurance cases, please contact Richard Chapman, Division of Software and Electrical Engineering, Office of Science and Engineering Laboratories at 301-796-2585 or via email at richard.chapman@fda.hhs.gov.

For questions regarding pre-clearance inspections, please contact Valerie Flournoy, General Hospital Devices Branch, Office of Compliance, at 301-796-5770 or via email at valerie.flournoy@fda.hhs.gov.

Thank you